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| APPLICATION NO.                         | FILING DATE                   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |  |
|---|-------------------------------|----------------------|-------------------------------|------------------|--|
| 08/714,987                              | 09/17/1996 HUGH SHARKEY 14:   |                      | 4170-014001/PT-2537-USNP 4099 |                  |  |
| <sup>26166</sup><br>FISH & RICHA        | 7590 01/15/200<br>ARDSON P.C. | EXAMINER             |                               |                  |  |
| SMITH & NEP                             | · ·                           |                      | SHAY, DAVID M                 |                  |  |
| 150 Minuteman Road<br>Andover, MA 01810 |                               |                      | ART UNIT                      | PAPER NUMBER     |  |
|   |                               |                      | 3769                          |                  |  |
|   |                               |                      |                               |                  |  |
|   |                               |                      | MAIL DATE                     | DELIVERY MODE    |  |
|   |                               |                      | 01/15/2009                    | PAPER            |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Advisory Action Before the Filing of an Appeal Brief

| Application No. | Applicant(s)   |  |
|-----------------|----------------|--|
| 08/714,987      | SHARKEY ET AL. |  |
| Examiner        | Art Unit       |  |
| david shay      | 3769           |  |

|  | david shay   | 3769  |  |
|--|--|---|--|
| The MAILING DATE of this communication appe  | ars on the cover sheet with the c  | correspondence add  | ress                                     |
| THE REPLY FILED <u>December 17, 2008</u> FAILS TO PLACE THIS   | S APPLICATION IN CONDITION F   | OR ALLOWANCE.   |  |
| 1. The reply was filed after a final rejection, but prior to or on application, applicant must timely file one of the following rapplication in condition for allowance; (2) a Notice of Appe for Continued Examination (RCE) in compliance with 37 C periods:   | the same day as filing a Notice of A<br>replies: (1) an amendment, affidavit<br>al (with appeal fee) in compliance               | Appeal. To avoid abar<br>t, or other evidence, w<br>with 37 CFR 41.31; or | hich places the (3) a Request            |
| a) The period for reply expiresmonths from the mailing b) The period for reply expires on: (1) the mailing date of this Ac no event, however, will the statutory period for reply expire la Examiner Note: If box 1 is checked, check either box (a) or (I MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f  | dvisory Action, or (2) the date set forth in<br>ter than SIX MONTHS from the mailing<br>b). ONLY CHECK BOX (b) WHEN THE          | g date of the final rejection   | n.                                       |
| Extensions of time may be obtained under 37 CFR 1.136(a). The date of have been filed is the date for purposes of determining the period of extrunder 37 CFR 1.17(a) is calculated from: (1) the expiration date of the set forth in (b) above, if checked. Any reply received by the Office later may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL | on which the petition under 37 CFR 1.1:<br>ension and the corresponding amount on<br>the tened statutory period for reply origin | of the fee. The appropria<br>nally set in the final Offic                 | ate extension fee<br>e action; or (2) as |
| 2. The Notice of Appeal was filed on A brief in compl filing the Notice of Appeal (37 CFR 41.37(a)), or any exter Notice of Appeal has been filed, any reply must be filed wi  | sion thereof (37 CFR 41.37(e)), to   | avoid dismissal of the  |  |
| 3. The proposed amendment(s) filed after a final rejection, b  (a) They raise new issues that would require further cor  (b) They raise the issue of new matter (see NOTE below  (c) They are not deemed to place the application in bett appeal; and/or   | isideration and/or search (see NOT<br>w);  | E below);   |  |
| (d) They present additional claims without canceling a converse NOTE: (See 37 CFR 1.116 and 41.33(a)).   |  |   |  |
| 4.  The amendments are not in compliance with 37 CFR 1.12 5.  Applicant's reply has overcome the following rejection(s):   | ·  |   | •  |
| <ol> <li>Newly proposed or amended claim(s) would be all non-allowable claim(s).</li> </ol>  | owabie ii submilled in a separale, l   | imely filed amendmer  | it canceling the                         |
| 7. For purposes of appeal, the proposed amendment(s): a) how the new or amended claims would be rejected is prove The status of the claim(s) is (or will be) as follows:  Claim(s) allowed:  Claim(s) objected to:  Claim(s) rejected:  Claim(s) withdrawn from consideration:   |  | l be entered and an ex  | xplanation of                            |
| AFFIDAVIT OR OTHER EVIDENCE  |  |   |  |
| <ol> <li>The affidavit or other evidence filed after a final action, but<br/>because applicant failed to provide a showing of good and<br/>was not earlier presented. See 37 CFR 1.116(e).</li> </ol>  |  |   |  |
| 9. The affidavit or other evidence filed after the date of filing a<br>entered because the affidavit or other evidence failed to or<br>showing a good and sufficient reasons why it is necessary   | vercome <u>all</u> rejections under appea  | ıl and/or appellant fail:   | s to provide a                           |
| 10.   The affidavit or other evidence is entered. An explanation   | n of the status of the claims after er   | ntry is below or attach   | ed.                                      |
| <ul> <li>REQUEST FOR RECONSIDERATION/OTHER</li> <li>11. The request for reconsideration has been considered but<br/>See Continuation Sheet.</li> </ul>   | does NOT place the application in  | condition for allowan   | ce because:                              |
| 12. Note the attached Information <i>Disclosure Statement</i> (s). (13. Other:   | PTO/SB/08) Paper No(s)   |   |  |
|  | /david shay/<br>Primary Examiner, Art U  | nit 3769  |  |

Continuation of 11. does NOT place the application in condition for allowance because: Applicant asserts that the statewment of Kirwin that "these areas should not overlap. In fact it is better to leave a small margin of untouched tissue about each one" constitutes a teaching away by Kirwin of providing adjacent or overlapping treatment areas. The examiner must respectfully disagree. The use of the term "should" rather than "must" in the quoted statement clearly shows that the provision of overlapping or adjacent treatment areas is merely a less preferred ambodiment of the method of Kirwin, compared to the prefferred embodiment of providing a small margin. Further, the teaching of Roth et al show the use of a technique where linear treatment areas, which overlap and/or are directly adjacent is a recognized treatment pattern in the art for reducing the bulk of the prostate in men experiencing BPH. In perfoming a method as taught by Roth et al. using the energy of Kirwin, or perfoming the method of Kirwin using the treatment pattern of Roth et al would result in the claimed back and forth motion, and the inclusion of a temperature sensor would inherently provide the claimed temperature sensing, particularly when the applicator is extended to its distal position pior to being rotated into the next reatment position, which would be the expected procedure, since both Kirwin and Roth et al emphasize the importance of temperature control in their procedures. Both Kirwin and Roth also discuss that it is the energy that is applied to the tissue that is of paramount importance, and thus one of ordinary skill in the art would understand that the energy could be varied in the method of Roth to allow for tissue contact as in the method of Kirwin, thus this argument is not vconvincing. Respecting applicant's assertion that the examiner has taken official notice regarding the production of linear leasions, the examiner must respectfull point out that the statement referred to is merely a summary of teachings found in Roth et al and Swanson et al. With regard to the arguments regarding the Sand reference, particularly with respect to claims 107 and 112, the examiner notes that the contacting of a joint is obvious in view of the teaching of Sand to treat connective tissues involving joints (e.g. ligaments and tendons), further especially when treating joints or connections between muscles and bones or bones and bones, the provision of an under treatment, rather than an overtreatment is clearly warrented, since an undertreatment (insufficient shrinkage) would simply result in a joint which is still too loose and which can easily be remedied by further treatment, which further treatment can proceed in view of the knowledge gained by the observation of the reaction of the tissue to the first treatment, and thus be more likely to approach the ideal desired joint tightness or stability, while overtreatment will rsult in a joint which hass too much shrinkage and will no longer have the original mobility. THerefore, given the fact that one of ordinary skill in the art is an orthopedic surgeon requiring not only 12 years of primary and secondary school, but 4 years of college, 4 more years of medical school, and additional years as an intern before qualifying to perfrom such surgeries, the ramifications of overtreatment and the advantage of approaching the desired degree of shrinkage from the direction of initial under treatment, rather than over treatment would not be lost on one of ordinary skill in the art. Lastly, regarding applicant's assertion of unexpected result, the examiner is at a loss to understand how one of ordinary skill in the art, especially one of ordinary skill in the art as set forth in the preceding sentence, would find the movement of a temperature sensing device toward an area which still contained residual heat to register a greater temperature then if it were moved away from such a site an "unexpected result". Thus this argument is also not convincing.